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Award Number: W81XWH-12-1-0567

TITLE: Effectiveness of Acupressure Treatment for Pain Management and Fatigue Relief in Gulf War Veterans

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CONTRACTING ORGANIZATION: Cleveland Clinic Foundation
Cleveland, Ohio 44195

REPORT DATE: October 2013

TYPE OF REPORT: Annual Report

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
October 2013	Annual Report	30September2012-29September2013

4. TITLE AND SUBTITLE

Effectiveness of Acupressure Treatment for pain Management and fatigue Relief in Gulf War Veterans

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-12-1-0567

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)
Vernon Lin MD PhD

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
Cleveland Clinic Foundation
Cleveland, Ohio 44195

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
This study will provide symptomatic veterans with acupressure treatment and determine its effectiveness in fatigue relief and pain management for GWI disease. We plan to recruit patients who report they have symptoms of GWI through the Department of Veterans Affairs (VA), and randomize them into acupressure group (to receive acupressure treatment) and control group (without acupressure treatment). The acupressure treatment, twice per week for 6 weeks, will be offered by licensed acupressure practitioner, with at least 5 years of clinical experience, who have received 20 hours of training related to symptoms of GWI. Evaluations will be made before and after treatment, and clinical outcomes will be compared between groups (acupressure group vs. control group) and between different stages (before treatment vs. after treatment) within the same group.

15. SUBJECT TERMS- none provided

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	6	19b. TELEPHONE NUMBER *(include area code)*

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I. INTRODUCTION

This study will provide symptomatic veterans with acupressure treatment and determine its effectiveness in fatigue relief and pain management for GWI disease. We plan to recruit patients who report they have symptoms of GWI through the Department of Veterans Affairs (VA), and randomize them into acupressure group (to receive acupressure treatment) and control group (without acupressure treatment). The acupressure treatment, twice per week for 6 weeks, will be offered by licensed acupressure practitioner, with at least 5 years of clinical experience, who have received 20 hours of training related to symptoms of GWI. Evaluations will be made before and after treatment, and clinical outcomes will be compared between groups (acupressure group vs. control group) and between different stages (before treatment vs. after treatment) within the same group.
Aim 1 is to investigate the effectiveness of acupressure for fatigue relief and pain management in veterans with GWI.
Aim 2 is to investigate the relationship between EEG measures, specifically the corticomuscular coherence and power spectra in theta band, and the clinical measures.

II. KEYWORDS

Acupressure, Reiki, Gulf War Illness, fatigue, chronic headache, musculoskeletal pain, electroencephalography, non-invasive, pain management, quality of life

III. STUDY PROGRESS

The research study was reviewed and fully approved by Cleveland Clinic IRB on 12/21/2012. The initial expiration date was 10/18/2013. DOD HRPO approval was received in February 20, 2013. The study received continuing renewal approval from Cleveland Clinic IRB and the approval expiration date is 10/18/2014.

The study is being conducted at only one site – Cleveland Clinic Foundation.

Investigational Site	Investigators
Cleveland Clinic Foundation 9500 Euclid Avenue, Cleveland, OH 44195	Vernon Lin MD PhD John Lee MD Juliet Hou MD Xiaofeng Wang PhD Guang Yue PhD Honglian Huang MD PhD Jamie Starkey LAc Xiaoming Zhang PhD Vinoth Ranganathan MSE MBA Shuyun Jiang MD (Consultant) Ernie Betz (Consultant – Reiki) Wenning Zhao (Consultant) Yin Fang PhD (Consultant) Vlodek Siemionow PhD (Consultant)

Due to unavailability of some of the personnel mentioned in the original proposal, changes were made to the research team (with DOD approval) and the study budget. Request to make these changes were sent to DOD and approval was received. Dr. Vernon Lin MD PhD replaced Yin Fang PhD as the study

PI. Xiaoming Zhang was hired as a research engineer to assist with data collection. Dr. Wenning Zhao and Ms. Alice Langholt were recruited to provide the Acupressure and Reiki interventions. Dr. Juliet Hou was recruited as a medical monitor. Dr. John Lee was included as a co-investigator to assist Dr. Lin with subject screening and recruitment. Further changes were requested in March 2013 to hire Honglian Huang MD PhD, a researcher with Oriental Medicine training to coordinate the study.

Dr. Huang was recruited in June and started her position as research coordinator from July 1, 2013. Alice Langholt was recruited in mid 2013 to provide Reiki therapy for the study. However, she relocated to Virginia in the fall of 2013 requiring the study team to search for another qualified Reiki master. Ernie Betz was identified as a qualified Reiki master and a contract will be signed with him in October 2013. The study team is working with him closely. The study team is continuing to screen subjects for the study.

Number of Subjects

The study has not enrolled any subjects. The study will be posted on the ClinicalTrials.gov website (pending approval) and advertised in local newspapers.

IV. KEY RESEARCH ACCOMPLISHMENTS

N/A

V. CONCLUSION

Due to unavailability of some of the personnel mentioned in the original proposal, significant changes were made to the research team (with DOD approval). Yin Fang PhD, the original PI, is no longer with Cleveland Clinic. He has been replaced by Dr. Vernon Lin (co-PI in the proposal). Also, the clinicans involved with providing the interventions have changed due to their inability to participate in the study. The changes in study personnel can delay study start-up and progress. To address the change in the investigative team, Dr. Lin has brought in experienced clinicans to provide the study interventions and assist with subject enrollment and study coordination. Dr. Fang will continue to participate in the study as a consultant.

The initial proposal included Cleveland VA as a recruitment site. However, per Cleveland VA recommendation, the study will now recruit subjects only at Cleveland Clinic. Study subjects will have to visit Cleveland Clinic two times per week for the intervention. This will limit the number of subjects willing and able to participate in the study. Limited access to Veterans outside Cleveland VA will also slow-down the enrollment. The study team will advertise in the local newspapers, Veterans support organizations and ClinicalTrials.Gov to attain proposed enrollment numbers. The study is being advertised on National Gulf War Resource Center's facebook page (thanks to Mr. James Bunker, Executive Director).

The study team will continue to screen and enroll subjects. Advertisements will be placed in local newspapers and Veterans support orgainzations. The study will also be posted on the ClinicalTrials.Gov website.

VI. PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS

N/A

VII. INVENTIONS, PATENTS AND LICENSES

N/A

VIII. REPORTABLE OUTCOMES

The study has not enrolled any subjects.

IX. OTHER ACHIEVEMENTS

N/A